IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

GARY WEBB,	)	
Plaintiff,	)	Civil Action No. 16-102
	)	
v.	)	Judge Cathy Bissoon
	)	
STRYKER CORPORATION, *et al*.,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

I. MEMORANDUM

For the reasons stated below, Defendants' Motion to Dismiss (Doc. 42) will be granted.

BACKGROUND

On August 31, 2012, Plaintiff underwent total left hip arthroplasty, during which a hip joint replacement system, consisting of a shell, insert, hip stem, femoral head and cap base manufactured by Stryker, was implanted. (Doc. 41 ¶ 33). Following the surgery, Plaintiff developed a wound infection. (Id. ¶ 16). In November 2012, he underwent surgery to remove the original hip implant and replace it with an antibiotic cement spacer. (Id.). A greater trochanteric osteotomy also was performed, with three cerclage cables inserted around the osteotomy. (Id. ¶ 20). On June 23, 2013, Plaintiff was diagnosed with a periprosthetic fracture around the cerclage cables. (Id. ¶ 23). On June 24, 2013, Plaintiff underwent a revision surgery, during which the cerclage wires and antibiotic spacer were removed and a total hip replacement with cable plate was performed. (Id. ¶¶ 24-27). Plaintiff claims that "Defendants designed the hip implants . . . with an inherent and unreasonable propensity . . . to fail to bond with the growth of the securing host bone, including loosening of the attachment between the bone and implants,

misalignment of the implant components and improper fit of the implant components, causing the hip implants to loosen and move in all affected patients[.]" (Id. ¶ 35). He also claims that "Defendants' negligent manufacturing and packaging of the hip implants were the direct and proximate cause of [his] development of an infection[.]" (Id. ¶ 51).

Plaintiff originally brought suit in the Court of Common Pleas of Beaver County for strict liability and negligence, based on three separate theories: negligent design, negligent manufacturing and failure to warn. The action was removed to this Court on January 21, 2016. Plaintiff filed what was styled his Second Amended Complaint (but which was, for reasons previously explained (Doc. 35 at 2), in actuality his *First* Amended Complaint) on June 2, 2016.

On November 21, 2016, upon motion by Defendants, the Court dismissed Plaintiff's claims for strict liability, with prejudice, and his claims for negligent design and manufacturing, without prejudice, while at the same time finding that he did state a viable failure-to-warn claim. (Doc. 35 at 7). Although the Court granted Plaintiff leave to amend with respect to the negligent design and manufacturing theories, it made clear that, if he chose to file another amended complaint, he had to "be prepared to make last, best efforts to state viable claim(s), as the Court [would] not afford further opportunity for amendment." (Id. at 7 n.2).

On December 29, 2016, Plaintiff filed his Fourth Amended Complaint,[1] reasserting his claims for negligent design (Count I), negligent failure to warn (Count II) and negligent manufacturing (Count III). (Doc. 41). Except where noted in the discussion that follows, the allegations in the Fourth Amended Complaint are the same as the allegations in the Second

[1] Plaintiff filed a Third Amended Complaint in response to the Court's Order regarding his Second Amended Complaint. (Doc. 36). However, after learning that the Court's Order was erroneously docketed as a Text Order without the analysis that was intended to accompany it, the Court permitted Plaintiff to file another amended complaint. (Doc. 40). That complaint, the Fourth Amended Complaint, is now the operative pleading. (Doc. 41).

Amended Complaint.

On January 12, 2017, Defendants filed a Motion to Dismiss with respect to Counts I and III. (Docs. 42-43). They also argue that any claims arising out of the device implanted during the second surgery should be dismissed because they have not been pled in the prior versions of the Complaint. On January 30, 2017, Plaintiff filed a response and brief in opposition (Docs. 44-45). On February 6, 2017, Defendants filed a reply (Doc. 46). The Motion is ripe for disposition.

ANALYSIS

A. *Negligent Design*

The Court dismissed the negligent design claim in Plaintiff's last amended complaint (Doc. 23), after determining that he failed to "identify the particular component of the hip implant alleged to have been defectively designed, let alone explain the nature of the alleged defect," and thus had not overcome the Twombly/Iqbal pleading standard. (Doc. 7 at 5). In the Fourth Amended Complaint, Plaintiff has attempted to address the deficiencies the Court observed by making a few minor modifications to his prior allegations and adding the following multi-part paragraph:

> 38. Defendants deviated from their duty to exercise reasonable care and were negligent, careless, and/or reckless in one or more of the following particulars:
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> a. In failing to properly design the original hip implant, consisting of the shell, insert, stem, femoral head and cap base and the subsequently installed acetabular component, plate, femoral stem, acetabular liner and femoral head (hereinafter referred to as "hip implant components") such that the hip implant components had adequate bonding qualities and propensities;
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> b. In failing to design the hip implant components such that the attachment between the hip implant components and bone would not be subject to loosening;

c. In failing to design the hip implant components such that they would fit properly with each other and with the host bone;

d. In failing to design the hip implant components such that they were aligned properly with each other and/or the host bone;

e. In failing to use proper materials in the design and manufacture of the hip implant components such that the components had adequate bonding qualities and propensities;

f. In failing to use proper materials in the design and manufacture of the original hip implant components such that the components where [sic] not susceptible to hosting and retaining bacteria and infection causing microorganisms;

g. In failing to design the hip implant components so as to minimize stress concentration among the inner relationship of the components and the host bone;

h. In failing to design the hip implant components so as to ensure that the hip implant would promote boney growth, thereby securing the prosthesis in place and preventing failure;

i. In failing to take appropriate action to correct the design of the hip implant components when Defendants knew or should have known that said components were failing at a rate and with a frequency and duration of use at acceptable levels;

j. In failing to conduct adequate clinical trials, testing and studies regarding the adequacy of design of the hip implant components; and

k. In failing to identify, correct and disclose in a timely fashion that the hip implants have design flaws that increase the risk of serious injury to patients undergoing total hip replacement.

(Doc. 41 ¶ 38).

While these allegations are lengthier and slightly more detailed than Plaintiff's prior efforts, they are nonetheless insufficient to state a claim under Twombly and Iqbal. As the Court previously emphasized, a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678

(2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). Mere "'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" Id. (quoting Twombly, 550 U.S. at 555).

Plaintiff once again has pled nothing more than "labels and conclusions." He still has not identified the particular component of the implant system (the shell, the insert, the stem, the femoral head or the cap base) that was defectively designed. More to the point, Plaintiff's claim fails because he has not pled any facts causally connecting the results of the purported design defect – the implant system's propensity to fail to bond and loosen – to the particular harm he suffered. In other words, he has not alleged that any particular component of the implant system actually used in his surgery failed to bond properly or came loose. Rather, as the Court understands the pleadings, Plaintiff had to have the antibiotic spacer implanted and undergo the revision surgery in June 2013 because of wound-infection, not any problem caused by bonding-failure or loosening of the components of the implant he received during his first surgery. Moreover, Plaintiff has not alleged that the "periprosthetic fracture around the proximal cerclage wire" that was diagnosed in June 2013 was caused by bonding-failure or loosening of any of the components of the implant he received in November 2013. Absent any such allegations, Plaintiff has not plausibly pled a negligent design claim, and Count I therefore will be dismissed.

B. *Negligent Manufacturing*

In dismissing Plaintiff's negligent manufacturing claim in its last Order, the Court concluded that Plaintiff's allegations were too conclusory to state a claim. The gist of Plaintiff's negligent manufacturing theory remains the same, but he has added the following paragraph in an effort to assuage the Court's misgivings:

> 50. Defendants breached their duty of care [by having] improper sanitary and nonsterile conditions at the point of manufacturing and packaging of the original hip implant components and/or due to an inherent susceptibility of the hip implant to cause infection due to improper design and/or manufacture. Specifically, Defendants were negligent in the following particulars:
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> a. By permitting the implants to be contaminated with micro-organisms, impurities and filth during the preparation and packaging process;
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> b. In failing to assure sanitary conditions at the point of manufacturing, including cleanliness of manufacturing equipment and packaging;
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> c. In permitting contamination of its hip implants through excessive manufacturing residuals; [and]
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> d. In failing to utilize methods, facilities and controls for the manufacture, packing, and storage of its hip implants in conformity with 21 U.S.C. § 351.
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> 51. The Defendants' negligent manufacturing and packaging of the hip implants were the direct and proximate cause of Plaintiff's development of an infection as a result of the original left total hip arthroplasty.

(Doc. 41 at ¶¶ 50-51).

These allegations still are too conclusory and vague to state a claim. Plaintiff has not specified what went wrong in the manufacturing process or explained how the "methods, facilities and controls for the manufacture, packing, and storage of the hip implants" fell below the FDA-imposed manufacturing standards imposed by 21 U.S.C. § 351, which defines when a drug or medical device is considered "adulterated," and the accompanying regulations. See Funk v. Stryker Corp., 631 F.3d 777, 782 (5th Cir. 2011) (dismissing similar manufacturing defect claim based on violation of FDA standards as "impermissibly conclusory and vague"). In addition, although he claims, in a general sense, that implants manufactured by Stryker were contaminated, he has not pled any facts from which the Court could infer that the particular

components *used in his surgery* were contaminated upon leaving the manufacturing facility. For example, Plaintiff has not alleged that any of his physicians determined that one, some or all of components of the implant system were contaminated or that they caused his infection.

Plaintiff essentially is claiming, without any factual allegations in support, that his infection *must* have been the result of Defendants' negligence – in other words, that the fact of his infection "speaks for itself" or *res ipsa loquitur*. But courts soundly have rejected efforts to apply *res ipsa loquitur* in cases involving medical devices, noting that "one may not infer a defect in the product simply because a patient encountered negative side effects in using it." Funk v. Stryker Corp., 673 F. Supp. 2d 522, 531 (S.D. Tex. 2009), aff'd, 631 F.3d 777 (5th Cir. 2011). As Judge Nora Barry Fischer has explained in a similar context, "[m]edical devices . . . inherently carry risks and the potential for harm to consumers, and negligence on behalf of the manufacturer is not necessarily the source of this harm." Gross v. Stryker Corp., 858 F. Supp. 2d 466, 499 (W.D. Pa. 2012). Therefore, it is incumbent upon a plaintiff in a case like this to "plead sufficient facts to rule out other possible causes of the aforementioned infection[.]" Id. Plaintiff has not done so here, and his negligent manufacturing claim will be dismissed.

C. *Claims Related to the June 2013 Implants*

Insofar as Plaintiff is now alleging that the components that were implanted during his June 2013 revision surgery were negligently designed and/or manufactured, the Court agrees with Defendants that any such claim is impermissible at this stage. The prior iterations of the complaint only challenged the implants used during the first surgery. When the Court dismissed the Second Amended Complaint, Plaintiff was given the opportunity to "make last, best efforts to state viable claim(s)." He was not given the opportunity to raise entirely new claims based on an entirely different hip replacement system (*i.e.*, the "Restoration Modular"). Thus, Plaintiff will

not be permitted to pursue these claims. In any event, any claims related to the implant utilized during the June revision surgery would fail for the same reasons Plaintiff's other claims fail: he has not plausibly alleged how this implant system was negligently designed or manufactured. On top of that, he has not alleged that any of the components used during this surgery failed in any way; nor has he alleged specific harm arising out of the revision surgery. Even if the Court were to allow Plaintiff to plead causes of action related to the implants used in the June 2013 surgery, the effort would be futile.

For all of the reasons stated above, the Court hereby enters the following:

II. ORDER

Defendants' Motion to Dismiss (Doc. 42) is **GRANTED**, and Counts I and III are **DISMISSED WITH PREJUDICE**. Defendants shall file an answer to Count II on or before **May 4, 2017**. See Fed. R. Civ. P. 12(a)(4)(A).

IT IS SO ORDERED.

April 20, 2017

s/ Cathy Bissoon
Cathy Bissoon
United States District Judge

cc (via ECF email notification):

All Counsel of Record